Long-term results of Talent endografts for endovascular abdominal aortic aneurysm repair

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Background: Since the introduction of endovascular aneurysm repair (EVAR), long-term follow-up studies reporting single-device results are scarce. In this study, we focus on EVAR repair with the Talent stent graft (Medtronic, Santa Rosa, Calif).

Methods: Between July 2000 and December 2007, 365 patients underwent elective EVAR with a Talent device. Patient data were gathered prospectively and evaluated retrospectively. By American Society of Anesthesiologists category, 74% were categories III and IV. Postoperative computed tomography (CT) scanning was performed before discharge, at 3, 12 months, and yearly thereafter. Data are presented according to reporting standards for EVAR.

Results: The mean proximal aortic neck diameter was 27 mm (range, 16-36 mm), with a neck length <15 mm in 31% (data available for 193 patients). Deployment of endografts was successful in 361 of 365 patients (99%). Initially, conversion to laparotomy was necessary in four patients. Primary technical success determined by results from computed tomography (CT) scans before discharge was achieved in 333 patients (91%). Proximal type I endoleaks were present in 28 patients (8%) during follow-up, and 14 of these patients needed additional treatment for type I endoleak. The 30-day mortality for the whole Talent group was 1.1% (4 of 365). Follow-up to 84 months is reported for 24 patients. During follow-up, 122 (33%) patients died; in nine, death was abdominal aortic aneurysm (AAA)-related (including 30-day mortality). Kaplan-Meier estimates revealed primary clinical success rates of 98% at 1 year, 93% at 2 years, 88% at 3 years, 79% at 4 years, 64% at 5 years, 51% at 6 years, and 48% at 7 years. Secondary interventions were performed in 73 of 365 patients (20%). Ten conversions for failed endografts were performed. Life-table yearly risk for AAA-related reintervention was 6%, yearly risk for conversion to open repair was 1.1%, yearly risk for total mortality was 8.9%, and yearly risk for AAA-related mortality was 0.8%.

Conclusion: Initially, technical success of endovascular aneurysm repair (EVAR) using the Talent endograft is high, with acceptable yearly risk for AAA-related mortality and conversion. However, a substantial amount of mainly endovascular reinterventions is necessary during long-term follow-up to achieve these results. (J Vasc Surg 2010;**:**:**:**.)

Endovascular aneurysm repair (EVAR) is widely accepted as an alternative for open repair. EVAR has proven to be a less invasive procedure compared with conventional, open repair surgery, with shorter procedure duration, reduced blood loss, shorter hospital stay, and significantly lower 30-day mortality rate.1,2 The drawback of EVAR is that secondary interventions are needed mainly to treat endoleaks, migration, graft disconnection, stent fractures, and graft thrombosis. Since the introduction of EVAR, many devices are now available for use, and commercially available devices have changed rapidly throughout the years, with improved flexibility and more secure proximal fixation. It is assumed that the ongoing improvements in graft design will lead to better long-term outcome and durability. Therefore, long-term follow-up studies are needed to evaluate the devices, although we have to keep in mind that long-term follow-up studies include EVAR procedures performed in the beginning of the EVAR era. In the past, we reported our experience with the AneuRx (Medtronic, Santa Rosa, Calif) stent graft.3,4 The Talent (Medtronic) stent graft is one of the most used devices worldwide and combines suprarenal fixation with high radial force and columnar strength. Long-term results of treatment with the Talent device are scarce and limited to small study populations.5,6 In this article, we report the 7-year results of the Talent graft gathered in two tertiary referral vascular medical centers. Data were collected prospectively and are retrospectively analyzed. Data are presented according to reporting standards for EVAR.7

PATIENTS AND METHODS

Patients were included from two hospitals, The St Antonius Hospital, Nieuwegein, The Netherlands, and Stanford University Hospital, Stanford, California, USA. Between July 2000 and December 2007, 365 patients underwent elective EVAR with the Talent graft. All aneurysms were infrarenal, and aneurysmatic extension to the iliac arteries was not excluded. Patients who were treated for a ruptured abdominal aortic aneurysm (AAA) were
excluded from the study. Inclusion for endovascular treatment was based on the individual surgeon’s decision. Exact data of anatomy and referral conditions were not available for all patients, but in both medical centers many patients had been referred by other surgeons after they were turned down for EVAR at other hospitals because of high-risk surgery (American Society of Anesthesiologists [ASA] score ≥3), and/or challenging anatomy (ie, infrarenal angulation >60 degrees, short neck length <15 mm, and >90 degrees iliac tract).

Data from all patients were recorded prospectively in a vascular database. The prospective data collection was coordinated between the two sites to capture similar data points, including the time intervals of the computed tomography (CT)-scans during follow-up. The database contains patient characteristics, graft characteristics, procedural characteristics, data concerning hospital stay, and follow-up data as readmissions, complications, occurrence of endoleaks, and all-cause mortality. Surveillance of patients after EVAR occurred at the outpatient department by regular clinical examination and CT scanning to rule out EVAR-related complications like endoleaks at regular time intervals, including before discharge, at 3, 12 months, and yearly thereafter. Ultrasound and X-rays were not used routinely for surveillance during the inclusion period of this study. In case of a negative CT scan but clinical high suspicion (ie, increase of AAA diameter) magnetic resonance angiography (MRA) with a specific setting for detecting (small) endoleaks or a selective angiography was performed. A radiologist and a vascular surgeon reviewed all follow-up CT scans for proper stent graft position, fixation, aneurysm diameter, and endoleak appearance. In case of long distance between patient’s home and our hospital, CT scans were performed locally. Scans were sent over for reviewing. If a patient did not appear for a regularly scheduled follow-up visit, the general practitioner was contacted for information about the patient’s condition.

According to the standards for EVAR, the following parameters of clinical outcome were reported:7

Survival outcomes. Overall survival and 30-day mortality, freedom from AAA-related death, and freedom from AAA rupture.

Technical success. Technical success relates to periprocedural events that occur from the initiation of the procedure and extend through the first 24-hour postoperative period. Primary technical success is defined by an intention-to-treat basis and requires successful deployment of the endovascular device at the intended location without death as a result of aneurysm-related treatment, type I or III endoleaks, graft infection or thrombosis, aneurysm expansion (increase of native aneurysm diameter >5 mm, or AAA volume >5%), aneurysm rupture, or conversion to open repair. Moreover, the presence of graft dilatation of ≥20% by diameter, graft migration, or a failure of device integrity classifies a case as a clinical failure.

Primary clinical success is clinical success without the need for an additional or secondary surgical or endovascular procedure. Assisted primary or secondary clinical success is clinical success achieved with the use of an additional endovascular or surgical procedure.

Statistical analysis. Data were analyzed using the SPSS 13.0 statistical software (SPSS Inc, Chicago, Ill). Kaplan-Meier curves and life tables were created with SPSS. We used nonparametric tests for continuous variables (Mann-Whitney test, Kruskal-Wallis test) and χ² and the Fisher exact test for categoric variables. When significant differences were found with the Kruskal-Wallis test, Dunn’s post hoc test was applied. Additionally, binary logistic regression analyses were used for multiple testing. Values of P < .05 were considered statistically significant.

RESULTS

Patient baseline characteristics are reported in Table I. Mean follow-up was 40 months (range, 1-106 months). For this study, we report follow-up to 84 months for 24 patients.
Technical success. Deployment of endografts was successful in 361 of 365 patients (99%). Initially, four patients required conversion to laparotomy. One conversion was to solve a large preoperative distal migration of the just placed stent graft in a patient with a large angulated neck, and in three patients, it was impossible to introduce the main device despite endovascular percutaneous transluminal angioplasty (PTA) procedures of the common iliac arteries. Primary technical success, based on results from CT scans before discharge, was achieved in 333 patients (91%). Primary proximal type I endoleaks were present in 28 patients (8%), and 14 (50%) of these 28 needed additional treatment during follow-up. The median time to treatment was 13 months. Treatment for these persistent primary type I endoleaks was: 8 proximal extension cuffs, 2 uni-iliac aortic stent grafts (AUI), 3 aortic neck plications, and 1 conversion to open repair. Causes of primary type I endoleak were: suboptimal placement in four, migration in seven, three suboptimal stent graft appositions. In 10 patients, type I endoleak resolved spontaneously within a maximum of 9 months after appearance, with no migration or enlargement of the native aneurysm during follow-up. In these patients follow-up with CT scan was intensified to 3-month intervals. No significant difference was determined between the limited numbers of patients with and without a spontaneous seal of a proximal type I endoleak in terms of neck angulation, diameter, and neck length. Details of extent of proximal neck thrombus and calcification were not recorded.

Four patients, with an early type I endoleak, died soon after the initial operation of non-AAA related causes (two of cardiac failures, one of multiorgan failure, and one of pneumonia).

Survival. Outcome is presented in Table II, including AAA-related mortality and all-cause mortality. Of the 365 patients overall, 122 (33%) died during follow-up. Estimated overall survival at 84 months by Kaplan-Meier curve was 50.4% (Fig 1). The freedom of AAA-related death is presented as a Kaplan-Meier survival curve (Fig 2). The Kaplan-Meier estimate for freedom of AAA-related death was 92% at 84 months. Nine AAA-related deaths (2.5%) occurred during follow-up. Four patients (1.1%) died within the first 30 days (above-mentioned). The other five patients died of complications of secondary interventions. One patient had non-
successful treatment of a type I endoleak. Eventually, the AAA ruptured and the patient died during open repair. The other patient underwent an open procedure after complicated femorofemoral crossover bypass and died due to myocardiac infarction in the ICU department. The other three patients, ASA class IV, died of rupture after unsuccessful secondary interventions for endoleaks and migration.

Four aneurysm ruptures (1.1%) occurred during follow-up. At 84 months, the Kaplan-Meier estimate for rupture-free survival is 96.5%.

Clinical success. Primary clinical success was achieved in 261 of 365 patients (71.5%) at a mean follow-up of 40 months. Data are displayed in Fig 3. Kaplan-Meier estimates revealed primary clinical success rates of 98% at 1 year, 93% at 2 years, 88% at 3 years, 79% at 4 years, 64% at 5 years, 51% at 6 years, 48% at 7 years, and 46.9% at 84 months. Primary-assisted clinical success rate was 81% (296 of 365) at a mean follow-up of 40 months, with a Kaplan-Meier estimate of 64.1% at 84 months. For the 104 patients who did not meet the criteria for primary clinical success, 73 patients underwent 73 additional procedures and 14 secondary procedures. An overview of the indications for reinterventions and the procedures performed are reported in Table III. The 14 secondary interventions comprised 4 conversions to laparotomy, 4 proximal extension cuffs, 2 femorofemoral crossover bypasses, 1 embolectomy, 1 PTA, 1 aortic neck wrapping, and 1 exploration to staunch a hemorrhage. In only two patients with endograft limb occlusions was thrombolysis used. In most of the patients with endograft (limb) occlusions an additional morphologic problem with the endograft limb was seen, like kinking or migration. These problems had to be treated with renewed stent grafts, or femorofemoral crossover bypass and were combined with open thrombectomy, instead of thrombolysis.

The remaining 31 of the 104 patients did not have a reintervention. Of the patients who did not receive additional treatment, 1 patient refused therapy for a type I endoleak, 2 had minor stent graft migrations, 1 had a small type III endoleak, and 4 patients died within 30 days. Twenty-three patients had AAA expansion >5 mm without presence of endoleaks or stent graft migration. These patients are in extensive follow-up with late phase CT and MRA scanning to detect the possible cause of AAA expansion.

Patients who did not reach clinical success criteria were compared with primary clinical successful patients. Compared were baseline AAA diameter, proximal aortic neck length, proximal aortic neck diameter, proximal endograft size (<32 mm vs ≥32 mm), ASA class, graft length and configuration (bifurcation, AUI, tube graft), and age. Mann-Whitney testing did not reveal statistical significances between the groups, including graft configuration and proximal diameter. However, there was a tendency (P = .07) for increasing age, larger AAA diameters, and shorter proximal aortic necks among patients who did not meet clinical success. Additionally, binary logistic regression analyses revealed larger AAA diameter was associated with clinical failures (P < .05).

Ten open conversions for failed endografts were performed, including initial conversions. The life-table yearly risk for AAA-related reintervention was 6%, yearly risk for conversion was 1.1%, and yearly risk for AAA-related mortality was 0.8%.

Table III. Indications for reinterventions and type of interventions

<table>
<thead>
<tr>
<th>Indications for reinterventions</th>
<th>Cases (No.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migration</td>
<td>11</td>
</tr>
<tr>
<td>Type I endoleak</td>
<td>21</td>
</tr>
<tr>
<td>Type II endoleak</td>
<td>9</td>
</tr>
<tr>
<td>Type III endoleak</td>
<td>1</td>
</tr>
<tr>
<td>Graft thrombosis/kinking</td>
<td>16</td>
</tr>
<tr>
<td>Infection</td>
<td>4</td>
</tr>
<tr>
<td>Postoperative hemorrhage</td>
<td>1</td>
</tr>
<tr>
<td>Rupture of aneurysm</td>
<td>1</td>
</tr>
<tr>
<td>Iliac stenoses</td>
<td>3</td>
</tr>
<tr>
<td>Renal artery stenoses</td>
<td>3</td>
</tr>
<tr>
<td>Unspecified</td>
<td>3</td>
</tr>
<tr>
<td>Interventions</td>
<td></td>
</tr>
<tr>
<td>Additional cuff placement</td>
<td>18</td>
</tr>
<tr>
<td>Coiling</td>
<td>8</td>
</tr>
<tr>
<td>Thrombolysis/thrombectomy/PTA</td>
<td>20</td>
</tr>
<tr>
<td>Femfem crossover bypass</td>
<td>5</td>
</tr>
<tr>
<td>Laparotomy, endograft explant</td>
<td>6</td>
</tr>
<tr>
<td>Abscess drainage</td>
<td>2</td>
</tr>
<tr>
<td>Staunch hemorrhage</td>
<td>1</td>
</tr>
<tr>
<td>Aortic monoiliac endoprosthes</td>
<td>6</td>
</tr>
<tr>
<td>Surgical control of lumbar endoleak</td>
<td>1</td>
</tr>
<tr>
<td>Aortic neck wrapping</td>
<td>5</td>
</tr>
</tbody>
</table>

PTA, Percutaneous transluminal angioplasty.
DISCUSSION

EVAR is widely accepted as a treatment for AAA. The long-term data of the Comparison of Endovascular Aneurysm Repair with Open Repair in Patients with Abdominal Aortic Aneurysm (EVAR-1) trial and the Dutch Randomized Endovascular Aneurysm Management (DREAM) trial were recently published.\(^8,9\) The long-term all-cause mortality did not differ between open surgery and the EVAR group. However, there was an initial benefit for EVAR due to a lower AAA-related mortality. EVAR-1 and other randomized trials were not designed to investigate the different EVAR devices, endograft capabilities and limitations, and device specific results.\(^1,2\) In daily practice, it is therefore useful that long-term data of frequently used EVAR devices, like the Talent device, are available.

Long-term results with other stent grafts have been published in the recent years. In 2009, Bos et al described their 5-year results with the Gore Excluder (W. L. Gore, Flagstaff, Ariz) stent graft.\(^10\) They showed an excellent long-term result with a 70% survival at 5-years with a 13% reinterventions rate and no AAA ruptures during follow-up. Abbruzzese et al analyzed the long-term device specific outcomes of the Cook Zenith (William A. Cook PTY LTD, Brisbane, Australia), Gore Excluder, and Medtronic AneuRx stent grafts and published comparable long-term outcomes.\(^11\) Overall 5-year survival rate was 61% with a reintervention rate of 20% and a 5-year AAA rupture rate of 1.1%. However, data are difficult to compare since the criteria for reporting standards for EVAR, published by Chaikof et al, are not used consequently.

Long-term results of the Talent graft are limited to a few studies.\(^5,12\) Through the years, indications for EVAR have changed. In the beginning, EVAR was more likely to be used as a therapy in patients who were unfit for open surgery. The studied population in this report also had severe comorbidities, reflected by the ASA classification presented in Table I. Besides high number of ASA 3 and 4 patients, a substantial part of patients was treated with EVAR in presence of challenging anatomy of the proximal neck (neck angulation ≥60 degrees, neck diameter ≥30 mm or neck length <15 mm, Table I). The overall mortality rate reported for this cohort is comparable with other series.\(^1,2,13\) Although long-term all-cause mortality is high in the current study, the 30-day mortality data of our cohort are good and even lower than in other series for EVAR and substantially lower than open repair.\(^1,2,8,12\) The EVAR-1 and DREAM trials showed an operative (30-day) mortality rate for the open-repair group of 4.7 and 4.6%, respectively.\(^1,2\) Aneurysm-related death and rupture in our study were limited and at least comparable to results reported in the randomized trials and registries.\(^13-15\) However, some under-registration of ruptured AAA could have occurred because postmortem examinations were not regularly performed.

Implantation and deployment of the graft was successful in 99% of the patients. Despite the Talent graft design with the ability of transrenal fixation by a 15-mm-long uncovered stent, primary technical success was still limited to 91%, mainly due to type I proximal endoleaks. An explanation for this could be the treating of a considerable number of patients with challenging AAA morphology, such as large and angulated (≥60 degrees) aortic necks. Detailed information about aortic neck length and diameters were available for 193 patients and information about neck angulation in 101 patients. The Talent graft was used to treat 60 patients with neck length <15 mm, which is likely to be a risk for a proximal type I endoleak. The presence of a perioperative detected type I endoleak is clinically relevant.

Perioperative additional procedures to solve a type I endoleak discovered on the completing angiography must be attempted. However, as described in the Results section, some endoleaks will spontaneously seal. In this cohort, 14 of 28 patients (50%) needed additional treatment for persistent type I endoleak during follow-up.

If no migration was seen, no AAA diameter or volume growth was noticed, and the position of the proximal endograft was optimal with regard to the lowermost renal artery, a watchful waiting policy was applied. In case of endograft migration with <1-cm fixation left, native AAA diameter, or volume growth, elective endovascular reintervention was scheduled. In most of the patients who needed an open reintervention procedure the intervention was postponed after persistent EVAR-related complications were diagnosed at a second control CT scan at 6 or 9 months.

During follow-up, clinical success was accomplished in almost half of the patients. A substantial number of patients underwent additional procedures. Most of these procedures were performed endovascularly, which limits patient comorbidity. Besides the mentioned number of endoleak problems, graft thrombosis and kinking were also issues. At the completion angiography of all patients, no kinking of the endograft limbs was predictable. Our data are consistent with other publications.\(^5,12\) During the follow-up years, reinterventions had to be performed consistently through all years. Regarding the Kaplan-Meier curve, a substantial increase in reinterventions could be observed in later years of follow-up. Therefore, regular and long-term clinical and radiologic surveillance is mandatory after a successful EVAR procedure.

This study is not without some limitations. Due to the retrospective character of this study, we do miss anatomical data such as the preoperative proximal suprarenal and infrarenal neck angulation in a substantial part of the patients and the existence of aneurysmal degeneration of the common iliac arteries.

Similar to all long-term follow-up studies for EVAR, we included patients over a long time interval. This means that a substantial number of patients were treated in the early days of our experience with the Talent device. Although we did not observe a decrease in EVAR-related complications over the years, there have been improvements in experience of EVAR at both institutions that will have been of influence in the study outcome. On the other hand, in both
institutes >500 EVAR procedures were performed with other devices before the Talent stent graft had been introduced.

The graft itself has evolved over the years (improved proximal fixation, a lower profile, and available in larger diameters up to 36 mm). These refinements in graft design could have influenced our results over the years.

Moreover, as the study progressed, the treatment boundaries were extended over the years, and patients with shorter and wider necks and increased angulation were treated, sometimes with violation of the instructions for use. This counteracts with the improvement in stent graft fixation characteristics.

One should also be aware that most of the included patients were referred by other hospitals and were denied for open as well for EVAR on bases of their anatomic characteristics and comorbidity in these (less experienced) centers, which might have introduced a selected patient group.

CONCLUSIONS

In this cohort with a high number of patients with severe comorbidity, overall mortality post-EVAR was substantial during follow-up. Technical success and clinical outcome are comparable to other manuscripts focusing on use of single EVAR devices. The current study showed (again) that the policy of treating higher risk patients with a suboptimal AAA anatomy for EVAR repair has its drawbacks including regularly and persistent follow-up and substantial need for reinterventions, which increases with follow-up duration.

AUTHOR CONTRIBUTIONS

Conception and design: BV, EW, FM, CZ, JV
Analysis and interpretation: BV, EW, JH, JV
Data collection: EW, MG
Writing the article: BV, EW
Critical revision of the article: JH, JV, FM, CZ, JV
Final approval of the article: BV, EW
Statistical analysis: BV
Obtained funding:
Overall responsibility: BV, FM, JV
BV and EW contributed equally to this work and share the first authorship.

REFERENCES


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